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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/819,669	03/17/1997	THIERRY BOON	LUD-5253.5-D	1995

24972 7590 02/06/2007
FULBRIGHT & JAWORSKI, LLP
666 FIFTH AVE
NEW YORK, NY 10103-3198

EXAMINER

GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
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1644

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

08/819,669

Applicant(s)

BOON ET AL.

Examiner

Phillip Gambel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 183-191 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 183-191 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's Response to Office Action, filed 12/12/06, has been entered.

Claims 183-191 are pending.

Claims have been canceled previously.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.

This Action will be in response to applicant's Response, filed 12/12/06.

The rejections of record can be found in the previous Office Action, mailed 12/6/06.

3. Applicant's comments concerning the prosecution history in the instant application are acknowledged.

At this point, there is no need to comment further on applicant's assertions concerning any delay in prosecution, other than to indicate that a number of issues have been addressed during the prosecution of the instant application, including correcting sequences and an appeal to the Board of Appeals and Interferences.

With respect to applicant's attempt to set forth the time for the examiner's response to two (2) weeks,

applicant is reminded that it is the USPTO that sets forth the proper time for responses to official communications and not applicant.

If applicant deems it necessary to take concerns to the Commissioner's Office directly for resolution, applicant is free to proceed according to their needs as deemed necessary.

However, applicant is reminded of Rule 1.2 (see MPEP) that:

All business with the Patent and Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

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4. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Also, see United States Patent and Trademark Office OG Notices: 1268 OG 89 (18 March 2003) for guidance concerning the proper manner to claim benefit of priority.

Applicant should amend the first line of the specification to indicate a specific reference to PCT/US92/04354 and its relationship to other applications for which benefit is sought.

Further, it is noted that the Oath/Declaration, filed 6/16/1997, indicates PCT/US92/04354 in its priority on page 1, yet this same PCT/US92/04354 is crossed-out on page 2.

Therefore, in addition to the absence of a reference to the PCT/US92/04354 in the claims for benefit of priority on the first page of specification,

there is ambiguity with respect to applicant's reliance on PCT/US92/04354 with respect to benefit of priority in the instant application.

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5. With respect to applicant's comments concerning the inventorship of U.S. Patent No. 5,843,448, filed as USSN 08/560,024; the following is noted.

Applicant asserts that U.S. Patent No. 5,843,448 issued with the incorrect inventorship on its due to USPTO error.

However, all U.S. Patents are presumed valid by U.S. Courts unless proven otherwise. See 35 USC 282.

Therefore, the inventorship of U.S. Patent No. 5,843,448 as currently listed on the patent is deemed to be correct.

Although applicant has provided copies of documents submitted in USSN 08/560,024, including a copy of a first request for a corrected filing receipt dated 8/7/1996, a second request for a correct filing receipt dated 10/19/1998 and a rush telefax set to Tajuanna Mills of the Publication Division on 11/23/1998 sending a copy of the signed declaration for co-inventors van der Bruggen and Boon-Falleur,

applicant is reminded that the action of the Patent and Trademark Office is based exclusively on the written record in the Office. See MPEP Rule 1.2.

The written record in U.S. Patent No. 5,843,448, filed as USSN 08/560,024, does not include a correction of inventorship to include van der Bruggen and Boon-Falleur as asserted by applicant, which is compliant with 37 CFR 1.67(a).

Applicant's attempts to correct inventorship via corrected filing receipts and faxes in USSN 08/560,024 does not appear to be compliant with the correction of inventorship under 37 CFR 1.67(a).

The correction of inventorship under 37 CFR 1.67(a) was requested by the Office throughout the prosecution of U.S. Patent No. 5,843,448, filed as USSN 08/560,024.

Therefore, the inventors of U.S. Patent No. 5,843,448 are those listed on the issued patent, namely Yao-Tseng Chen, Elisabeth Stockert, Pilar Garin-Chesa, Wolfgang J. Rettig and Lloyd J. Old.

Currently, there is no inventor in common between of U.S. Patent No. 5,843,448 and the instant USSN 08/819,669.

It appears that applicant's representative has admitted that inventorship of U.S. Patent No. 5,843,448, filed as USSN 08/560,024 is incorrect and that applicant's representative has had knowledge of this during the prosecution of USSN 08/560,024 and subsequent to the issuance of U.S. Patent No. 5,843,448.

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With respect to applicant's request for "immediate action", correcting the inventorship of U.S. Patent No. 5,843,448, filed as USSN 08/560,024, is the burden of those responsible for U.S. Patent No. 5,843,448, filed as USSN 08/560,024 and not within the purview of the instant application, nor the burden of this examiner, nor the USPTO.

Applicant is invited to consider filing a petition in an attempt to correct the inventorship of U.S. Patent No. 5,843,448, filed as USSN 08/560,024.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --
(f) he did not himself invent the subject matter sought to be patented.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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8. Claims 183-191 are rejected under 35 U.S.C. § 102(f) or, in the alternative, under 35 U.S.C. 102(f)/103(a) because the applicants did not invent the claimed subject matter essentially for the reasons of record.

It is noted that SEQ ID NO: 8 of the instant USSN 08/819,669 is the same sequence as SEQ ID NO: 1 disclosed in Example 5 of U.S. Patent No. 5,843,448 (see 892, mailed 3/28/01) (e.g., see Example 5 on columns 7-8 of U.S. Patent No. 5,843,448).

The patented claims of U.S. Patent No. 5,843,448 are drawn to MAGE-1 tumor rejection antigen precursor proteins and immunogenic compositions, which anticipate the instant MAGE tumor rejection antigen precursor proteins and compositions thereof. Further, it has been well known for decades by the ordinary artisan that vaccines and immunogenic compositions often comprise an adjuvant to increase the immunogenicity of the immunogenic or vaccine composition of interest.

Applicant's arguments, filed 12/12/06, have been fully considered but have not been found convincing essentially for the reasons of record.

In response to applicant's assertions that the inventions must be the same for a 102(f) rejection to be proper,

the 102(f) / 102(f)/103(a) rejection has been set forth to encompass the issues of the claimed subject under 102(f) for the purposes of Sections 102 and 103.

In contrast to applicant assertions,
the examiner has not misread the claims, has not misinterpreted the law and has reviewed the cases carefully.

With respect to applicant's assertions that the examiner is estopped from making the rejection under 35 USC 102(f),

it is well settled that whether similar claims have been allowed to others is immaterial.

See In re Giolito, 188 USPQ 645 (CCPA 1976) and Ex parte Balzarini, 21 USPQ2d 1892, 1897 (BPAI 1991).

Again, as indicated previously and addressed above,
it is noted that U.S. Patent No. 5,843,448 does not have a common inventor with the instant application.

Further, applicant's Response to Office Action, filed 12/12/06, clearly indicates that the inventorship of U.S. Patent No. 5,843,448 is incorrect, which, in turn, supports the ambiguity about inventorship raised in the rejection under 102(f) in the previous Office Action, mailed 9/7/06.

Applicant's assertions that the inventions must be the same, implying that the claims must exactly the same for a proper rejection under 102(f) is not consistent with legal precedent or guidance from the MPEP.

Where it can be shown that an applicant derived an invention from another, a rejection under 35 USC 102(f) is proper. See MPEP 706.02(g) and MPEP 2137.

Prior art under 35 USC 102(f) may be available under 35 USC 103.

See OddzOn Products, Inc. v. Just Toys, Inc., 43 USPQ2d 1641, 1644 (Fed. Cir. 1997)(35 U.S.C. "102(f) is a prior art provision for purposes of § 103"); Dale Electronics v. R.C.L. Electronics, 180 USPQ 225, 227 (1st. Cir. 1973); and Ex parte Andresen, 212 USPQ 100, 102 (Bd. App. 1981).

See MPEP 2004 and MPEP 706.02(l).

Further, it is noted that derivation is key to a rejection under 35 USC 102(f) and that derivation addresses originality (i.e. who invented the subject matter).

See MPEP 2137.

Also, for conception of specific compounds, one must have a mental picture of the structure or of other characteristics that distinguish it from the prior art.

See Board of Education ex rel board of Trustees of Florida State University v American Bioscience Inc., 67 USPQ2d 1252 (Fed Cir 2003).

Also, see MPEP 2137.01 and 2138.04.

Here, while the recitation of the instant claims does not recite MAGE-1 per se, the instant claims recite a MAGE tumor rejection tumor antigen precursor encoded by the nucleic acid molecule, the complementary sequence of which hybridizes to SEQ ID NO: 8.

SEQ ID NO: 8 of instant USSN 08/819,669 is specifically drawn to MAGE-1.

While the recitation of the issued claims in U.S. Patent No. 5,843,448 does not recite a SEQ ID NO. per se,

the issued claims of in U.S. Patent No. 5,843,448 are drawn to MAGE-1 tumor rejection antigen precursors and SEQ ID NO: 1 disclosed in Example 5 in U.S. Patent No. 5,843,448 encoding MAGE-1 tumor rejection antigen precursor is the same sequence as SEQ ID NO: 8 of instant USSN 08/819,669.

Further, it is noted that the instant claims are not limited to tumor rejection antigen precursors comprising / consisting of SEQ ID NO: 8 only.

Also, it is noted that the issued claims of U.S. Patent No. 5,843,448 are not limited to a single species either.

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While the scope of the instant and issued claims differ, both sets of claims are clearly drawn to or based upon the same or nearly the same reference sequence encoding tumor rejection antigen precursors, namely SEQ ID NO: 8 in the instant USSN 08/819,669 or SEQ ID NO: 1 in U.S. Patent No. 5,843,448.

It is the base or reference sequence structure encoding tumor rejection antigen precursors (namely SEQ ID NO: 8 in the instant USSN 08/819,669 or the structural limitations comprising SEQ ID NO: 1 in U.S. Patent No. 5,843,448 that is the key characteristic that distinguishes the instant claims from the prior art

Given the base structural characteristics (e.g., sequence, MAGE-1) common to both the instant and patented claims, the instant and patented claims would anticipate one another.

In addition to the anticipation of instant and issued claims over one another, the instant and issued claims both encompass overlapping MAGE tumor rejection antigen precursors encompassing some variability in the structure of said tumor rejection antigen precursors, wherein the in tumor rejection antigen precursors are encoded by nucleic acids, the complementary of which hybridizes to SEQ ID NO: 8 (see instant claims) or have a molecular weight of about 34.3 - 46 kilodaltons (see claims of U.S. Patent No. 5,843,448) (or SEQ ID NO: 1; see Example Example 5 of U.S. Patent No. 5,843,448).

Further, the record in the instant application clearly indicates that the instant inventorship was responsible for isolating and identifying instant SEQ ID NO: 8 as encoding MAGE tumor rejection antigen precursors (e.g., see Declarations submitted 7/9/98, 6/30/00, 7/10/00 by the instant inventorship to correct SEQ ID NO: 8.).

Again, as pointed out previously and addressed herein,

Given the presumption of validity of U.S. Patent No. 5,843,448 and that no inventors are in common between the instant USSN 08/819,669 and U.S. Patent No. 5,843,448, there is ambiguity as to who invented the claims drawn to MAGE tumor rejection antigen precursor proteins, including MAGE-1 or SEQ ID NO: 8 recited in the instant claims, forming the basis of the instant MAGE tumor rejection antigen precursor proteins.

Applicant's arguments have not been found persuasive and the rejection is maintained for the reasons of record as well as applicant's admissions that the inventorship of U.S. Patent No. 5,843,448 is incorrect.

Because of the ambiguity of the inventorship, it is incumbent on applicant to provide a satisfactory showing, which would lead to a reasonable conclusion that the instant listed inventorship are the sole inventors of the claimed invention.

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9. Upon filing a terminal disclaimer on 12/12/2006, the previous rejection under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of commonly assigned U.S. Patent No. 5,843,448 has been withdrawn.

The terminal disclaimer filed on 12/12/2006, disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of U.S. Patent No. 5,843,448 has been reviewed and is accepted.

The terminal disclaimer has been recorded.

10. Claims 183-191 are directed to an invention not patentably distinct from claims 1-9 of commonly assigned U.S. Patent No. 5,843,448 for the reasons of record set forth in the previous Office Action, mailed 12/6/06.

Although the claims are not the same, the patented claims, drawn to MAGE-1 tumor rejection antigen precursors and immunogenic compositions anticipate the instant MAGE tumor rejection antigen precursor proteins and compositions. It has been well known by the ordinary artisan for decades that vaccines are immunogenic and often comprise an adjuvant to increase the immunogenicity of the immunogenic or vaccine composition of interest.

Further, it is noted that SEQ ID NO: 8 of instant USSN 08/819,669 is the same as SEQ ID NO: 1 disclosed in Example 5 of U.S. Patent No. 5,843,448 (e.g., see Example 5 on columns 7-8 of U.S. Patent NO. 5,843,448).

Also, note that SEQ ID NO: 8 of the instant USSN 08/819,669 acknowledges that SEQ ID NO: 8 is a nucleic acid sequence encoding MAGE-1 (see Brief Description of the Sequences on page 10 of the instant specification). MAGE-1 is the subject of the patented claims and Example 5 of U.S. Patent No. 5,843,448.

Therefore, the instant claims and patented claims can anticipate or render obvious one another.

As indicated in the previous Section, applicant has filed a Terminal Disclaimer in response to the obvious-type double patenting rejection of record.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned U.S. Patent No. 5,843,448, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. ***In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.***

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A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Again, it is noted that there is no inventor in common between the instant USSN 08/819,669 and U.S. Patent No. 5,843,448.

Also, as noted in MPEP 804.03, applicant is reminded that:

Applications or patents are "commonly owned" pursuant to 35 U.S.C. 103(c)(1) if they were wholly or entirely owned by the same person(s), or organization(s)/business entity(ies), at the time the claimed invention was made. See MPEP § 706.02(l)(2) for a detailed definition of common ownership. < Two inventions of different inventive entities come within the >common ownership< provisions of 35 U.S.C. 103(c)>(1)< when:

(A) the later invention is not anticipated by the earlier invention under 35 U.S.C. 102;

(B) the earlier invention qualifies as prior art for purposes of obviousness under 35 U.S.C. 103 against the later invention only under *>subsections< (f) or (g) of 35 U.S.C. 102, or >under< 35 U.S.C. 102(e) for applications >pending on or after December 10, 2004, for reexamination proceedings in which the patent under reexamination was granted on or after December 10, 2004, and for reexamination proceedings in which the patent under reexamination was< filed on or after November 29, 1999; and

(C) the inventions were, at the time the later invention was made, owned by the same person or subject to an obligation of assignment to the same person

Here again, as pointed out previously, applicant is reminded that common ownership means wholly or entirely owned by the same at the time the invention was made and that the patented claims anticipate the instant claims.

As noted above and clearly indicated in applicant's Response to Office Action, filed 12/12/06, the inventorship of U.S. Patent No. 5,843,448 is incorrect.

Applicant's arguments concerning the inventorship and issues related to this Section have been fully considered but have not been found persuasive for the reasons of record and that addressed above.

Applicant has not provided a statement regarding the common ownership at the time the invention was made.

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11. It is noted that applicant has a number of copending applications in the instant family of applications encompassing MAGE tumor rejection antigen precursors that anticipate or render obvious the instant claims.

Again, given the history of a number of continuations-in-part, it is not readily apparent whether the claims were subject to restriction and whether the claims are subject to double patenting rejections.

Applicant is invited to clarify which applications should be subject to rejections under the judicially created doctrine of obviousness-type double patenting.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-272-8300.

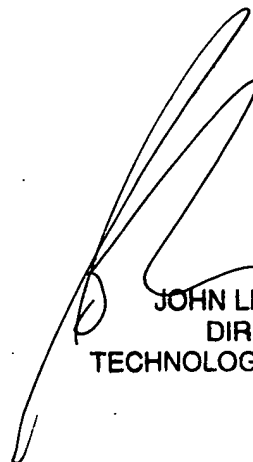
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Phillip Gambel, Ph.D., J.D.
Primary Examiner
Technology Center 1600
January 30, 2007



CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600



JOHN LEGUYADER
DIRECTOR
TECHNOLOGY CENTER 1600